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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,453	06/06/2001	Jungshuh P. Kim	4600-0135.30	7454

7590 12/24/2002
Perkins Coie LLP
P. O. Box 2168
Menlo Park, CA 94026

EXAMINER

SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/875,453

Applicant(s)
Kim et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 2, drawn to an isolated nucleic acid, SEQ ID NO:5, which is a regulatory sequence for a cyclin D1 promoter, classified in class 536, subclass 23.1.
 - II. Claims 1 and 2, drawn to an isolated nucleic acid, SEQ ID NO:6, which is a regulatory sequence for a cyclin D1 promoter, classified in class 536, subclass 23.1.
 - III. Claims 1 and 2, drawn to an isolated nucleic acid, SEQ ID NO:8, which is a regulatory sequence for a cyclin D1 promoter, classified in class 536, subclass 23.1.
 - IV. Claims 3 and 4, drawn to an isolated nucleic acid, SEQ ID NO:12, which is a regulatory sequence for a CD40L promoter, classified in class 536, subclass 23.1.
 - V. Claims 3 and 4, drawn to an isolated nucleic acid, SEQ ID NO:13, which is a regulatory sequence for a CD40L promoter, classified in class 536, subclass 23.1.
 - VI. Claims 3 and 4, drawn to an isolated nucleic acid, SEQ ID NO:14, which is a regulatory sequence for a CD40L promoter, classified in class 536, subclass 23.1.

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- VII. Claims 3 and 4, drawn to an isolated nucleic acid, SEQ ID NO:15, which is a regulatory sequence for a CD40L promoter, classified in class 536, subclass 23.1.
- VIII. Claims 5, 6 and 7, drawn to an isolated nucleic acid, SEQ ID NO:20, which is a regulatory sequence for a HBV core promoter, classified in class 536, subclass 23.1.
- IX. Claims 5, 6 and 7, drawn to an isolated nucleic acid, SEQ ID NO:21, which is a regulatory sequence for a HBV core promoter, classified in class 536, subclass 23.1.
- X. Claims 5, 6 and 8, drawn to an isolated nucleic acid, SEQ ID NO:23, which is a regulatory sequence for a HBV preS1 promoter, classified in class 536, subclass 23.1.
- XI. Claims 5, 6 and 8, drawn to an isolated nucleic acid, SEQ ID NO:24, which is a regulatory sequence for a HBV preS1 promoter, classified in class 536, subclass 23.1.
- XII. Claims 5, 6 and 9, drawn to an isolated nucleic acid, SEQ ID NO:26, which is a regulatory sequence for a HBV X promoter, classified in class 536, subclass 23.1.
- XIII. Claims 5, 6 and 9, drawn to an isolated nucleic acid, SEQ ID NO:27, which is a regulatory sequence for a HBV X promoter, classified in class 536, subclass 23.1.
- XIV. Claims 5, 6 and 9, drawn to an isolated nucleic acid, SEQ ID NO:28, which is a regulatory sequence for a HBV X promoter, classified in class 536, subclass 23.1.

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- XV. Claims 10 and 11, drawn to an isolated nucleic acid, SEQ ID NO:32, which is a regulatory sequence for a vancomycin-resistant enterococci (VRE) promoter, classified in class 536, subclass 23.1.
- XVI. Claims 10 and 11, drawn to an isolated nucleic acid, SEQ ID NO:33, which is a regulatory sequence for a vancomycin-resistant enterococci (VRE) promoter, classified in class 536, subclass 23.1.
- XVII. Claims 10 and 11, drawn to an isolated nucleic acid, SEQ ID NO:34, which is a regulatory sequence for a vancomycin-resistant enterococci (VRE) promoter, classified in class 536, subclass 23.1.
- XVIII. Claims 12 and 13, drawn to an isolated nucleic acid, SEQ ID NO:64, which is a regulatory sequence for an androgen receptor (AR) promoter, classified in class 536, subclass 23.1.
- XIX. Claims 12 and 13, drawn to an isolated nucleic acid, SEQ ID NO:65, which is a regulatory sequence for an androgen receptor (AR) promoter, classified in class 536, subclass 23.1.
- XX. Claims 12 and 13, drawn to an isolated nucleic acid, SEQ ID NO:66, which is a regulatory sequence for an androgen receptor (AR) promoter, classified in class 536, subclass 23.1.
- XXI. Claims 14 and 15, drawn to an isolated nucleic acid, SEQ ID NO:70, which is a regulatory sequence for a HER2 promoter, classified in class 536, subclass 23.1.

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XXII. Claims 14 and 15, drawn to an isolated nucleic acid, SEQ ID NO:71, which is a regulatory sequence for a HER2 promoter, classified in class 536, subclass 23.1.

XXIII. Claims 14 and 15, drawn to an isolated nucleic acid, SEQ ID NO:72, which is a regulatory sequence for a HER2 promoter, classified in class 536, subclass 23.1.

XXIV. Claims 16 and 17, drawn to an isolated nucleic acid, SEQ ID NO:77, which is a regulatory sequence for a beta lactamase (Bla) promoter, classified in class 536, subclass 23.1.

XXV. Claims 16 and 17, drawn to an isolated nucleic acid, SEQ ID NO:78, which is a regulatory sequence for a beta lactamase (Bla) promoter, classified in class 536, subclass 23.1.

XXVI. Claim 25, drawn to a method of modulating expression with a compound which binds to a promoter regulatory sequence, classified in class 435, subclass 91.1.

Claims 18-24 are generic to Groups I-XXV and will be examined as they pertain to the subject matter of the elected Group.

Claims 18 and 19 are generic to Group XXVI and will be examined as they pertain to the subject matter of the elected Group.

Claim 1 links inventions of Groups I-III. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 1. Claim 3 links inventions of Groups IV-VII. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 3. Claim 5 links inventions of Groups VIII-XIV. The

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restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 5. Claim 10 links inventions of Groups XV-XVII. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 10. Claim 12 links inventions of Groups XVIII-XX. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 12. Claim 14 links inventions of Groups XXI-XXIII. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 14. Claim 16 links inventions of Groups XXIV-XXV. The restriction requirement applied to the linked inventions is subject to the nonallowance of the linking claim 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are independent and/or distinct, each from the other because of the following reasons: Inventions of Groups I and II-XXV are unrelated. Inventions are unrelated

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if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions of Groups I-XXV are unrelated because each of Groups I-XXV is drawn to a independent and/or distinct nucleic acid sequence.

3. Groups I-XXV and Group XXVI are comprised of multiple inventions which are the products or methods drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. If any of Groups I-XXV and XXVI are elected, applicants must elect a single invention which is the product or method drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the office no longer permit examination of more than one sequence in an application.

4. Because these inventions are distinct for the reasons given above and the search of the nucleic acid sequence database required for each of Groups I-XXV is not required for each of the other Groups I-XXV, and because the inventions of Groups I-XXV are distinct from the invention of Group XXVI for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the customer service center, whose telephone number is (703) 308-0198.

William Sandals, Ph.D.

Examiner

December 14, 2002


TERRY MCKELVEY
PRIMARY EXAMINER